UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NORTH CAROLINA
SOUTHERN DIVISION

No. 7:12-CV-23-F

JOEL CAPLIN, Individually and on Behalf of All Others Similarly Situated, Plaintiffs,	)	
v.	)	ORDER
TRANS1, INC., KENNETH REALI, JOSEPH P. SLATTERY, RICHARD RANDALL, and MICHEAL LUETKEMEYER, Defendants.	)	

This matter is before the court on the Defendants' (collectively, "TranS1")[1] motion to dismiss [DE-34].[2] Plaintiffs (collectively, "Caplin") have filed a response in opposition [DE-41]. The motion has been fully briefed and is ripe for ruling.

PROCEDURAL AND FACTUAL BACKGROUND

Caplin initiated this action on January 4, 2012, by filing a Class Action Complaint [DE-1] alleging claims for violations of the federal securities laws. Caplin timely filed an Amended Class Action Complaint [DE-29], which TranS1 now moves to dismiss. By its May 8, 2012 Order [DE-27], the court appointed Philip J. Singer as lead Plaintiff and the law firm Pomerantz, Haudek, Grossman & Gross, LLP as lead counsel.

[1] TranS1 has recently changed its corporate name to Baxano Inc, and filed an unopposed motion to change the caption of the case [DE-45]. The court will address that motion below.

[2] The plaintiffs have also filed a number of "requests for judicial notice" [DE-43, -46, -47] related to the motion to dismiss. The court will address these motions below as well.

For purposes of ruling on a Rule 12(b)(6) motion to dismiss, the court assumes that the well-pleaded factual allegations in the amended complaint are true. *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009). The court therefore relates the facts as alleged in the amended complaint and as Caplin describes them in its response in opposition to the motion to dismiss [DE-41] ("Caplin Resp."). The court notes that TranS1 disputes much of Caplin's version of the facts.

TranS1 is a publicly-traded medical device company that designs, markets, and sells medical devices used in spinal procedures. The AxiaLIF line of products is the company's primary source of revenue. AxiaLIF is a type of spinal surgery in which the surgeon performs spinal fusion and motion preserving surgeries utilizing a "pre-sacral approach." The pre-sacral approach allows the patient to remain on his stomach throughout the procedure as the surgeon performs the procedure straight up the tailbone. This procedure is different than most spinal surgeries, which utilize an "anterior" or frontal approach, where the surgery is performed through the frontal portion of the spine with the patient positioned on his back.

Utilization of the AxiaLIF procedure, and consequently the AxiaLIF line of products, is dependent on surgeons receiving reimbursement from third-party payors (health insurance providers). Thus, TranS1's revenue is highly dependent on whether health insurance providers will reimburse for the procedure. As Caplin notes in his brief, "[i]f insurace companies refuse to reimburse surgeons for an AxiaLIF procedure, they will simply stop utilizing the device." Caplin Resp. [DE-41] at 4.

TranS1 initially obtained FDA approval to manufacture and sell the AxiaLIF line of products through the 510(k) approval process, which is less costly and rigorous than the typical FDA pre-market approval process for medical devices. Importantly, the 510(k) approval process

requires less supporting research data regarding effectiveness than the traditional pre-market approval process.

After TranS1 obtained FDA approval, it began the process of ensuring that surgeons would receive health insurance reimbursement for performing the AxiaLIF procedure and using the related medical devices. Insurance reimbursement decisions are dependent on the American Medical Association's (AMA) "Current Procedural Terminology" (CPT) codes. The CPT system divides physician services into three distinct categories and eligibility for reimbursement for a particular procedure is often dependent on the procedure's CPT code. Category III is typically reserved for newer or experimental procedures in which a limited amount of research data is available regarding safety and effectiveness. Various federal statutes require surgeons to use the appropriate CPT code on reimbursement forms.

Prior to 2009, surgeons could code the AxiaLIF procedure as an anterior fusion procedure under Category I and easily obtain reimbursement from insurance providers.[3] In 2008, on the recommendation of the National Association of Spine Surgeons Reimbursement Coding Committee, the AMA changed the CPT code for AxiaLIF to Category III. Both the AMA and the National Association of Spine Surgeons were concerned about the lack of research data regarding the safety and effectiveness of the AxiaLIF procedure and the fact that the procedure did not employ the traditional anterior approach through the front of the spine. The new Category III CPT code became effective January 1, 2009. After the new designation, most

[3] The parties' briefing does not make clear why the AMA allowed AxiaLIF to be coded as a Category I, anterior procedure prior to 2009. Because the alleged fraud did not take place until after the AMA changed the CPT code to Category III, however, the issue is not relevant for purposes of the motion to dismiss.

insurance providers refused to reimburse surgeons performing the AxiaLIF procedure, allegedly "threatening the future viability of [TranS1]." *Id.* at 5.

Caplin alleges that in response to the Category III designation, TranS1 engaged in a pervasive fraudulent scheme in which it "coached" physicians to avoid the Category III CPT code to obtain reimbursement for the AxiaLIF procedure. The fraudulent scheme involved multiple components: a reimbursement committee which presented information to surgeons regarding how to avoid or conceal the Category III designation; illicit conference calls with distributors in which TranS1 instructed its distributors to advise surgeons to use a Category I CPT code for the AxiaLIF procedure; training sessions and development of a coding template designed to "coach" surgeons to avoid or conceal the Category III designation; a reimbursement guide advocating various methods for concealing the Category III designation; and national meetings in which TranS1 instructed physicians and other employees in various methods to avoid the Category III designation. Much of the evidence for the allegations comes from confidential witnesses who are former employees of the firm.

A. Reimbursement Committee

After the Category III designation was announced, TranS1's senior management (the individual defendants) allegedly formed a "reimbursement committee" headed by Amy Conner. The reimbursement committee allegedly gave presentations to surgeons regarding how to fraudulently obtain reimbursement despite the Category III designation and created a hotline in which surgeons received telephonic coaching in which they were instructed to conceal the designation. The presentations and telephonic coaching advised surgeons to "bury" the Category III designation at the bottom of the reimbursement form so insurance providers would likely

overlook the code and provide coverage. The confidential witnesses also report that Conner gave presentations to senior management regarding the process for avoiding the Category III designation.

B. Illicit Conference Calls with Distributors

The confidential witnesses also report that TranS1 employees held conference calls with distributors of the AxiaLIF line of products in which employees encouraged distributors to advocate use of the Category I CPT designation to surgeons instead of the required Category III designation. TranS1 advised the distributors to tell surgeons that all surgeons coded the AxiaLIF procedure in this manner, despite the AMA mandate. The confidential witness involved in these conference calls allegedly stated, "TranS1 told us to do whatever we had to do [to get surgeons to use its product]." *Id.* at 8.

C. Training Sessions and Coding Template

TranS1 also allegedly held onsite training sessions regarding coding procedures for AxiaLIF at locations where surgeons performed the procedure. Dr. William Tobler was one of TranS1's primary physician consultants during the class period and he provided many of these onsite training sessions. During the sessions, Dr. Tobler promoted use of the AxiaLIF procedure and advised the surgeons that it could be coded as a Category I procedure. TranS1 also allegedly directed Dr. Tobler to create a "reimbursement template" that contained instructions regarding coding AxiaLIF as an anterior procedure, which allowed for a Category I designation. The template implied that surgeons could disguise the fact that the operation was an AxiaLIF procedure by recording post-operation notes suggesting that the procedure was a Category I anterior procedure. A confidential witness confirmed the existence of the reimbursement

template and was allegedly present at the training sessions in which AxiaLIF was performed on cadavers and surgeons were subsequently encouraged to code it as a Category I procedure.

D. Reimbursement Guide

In addition to the reimbursement template, the amended complaint alleges that TranS1 developed and distributed a "reimbursement guide." The guide lists multiple CPT codes that "may be appropriate during an AxiaLIF procedure," the majority of which are not the required Category III code. *Id.* at 10. The last page of the guide alerts surgeons that the AMA has assigned the Category III code. Acknowledging that insurance providers may deny claims based on the Category III designation, the guide encourages physicians to use alternative codes to obtain reimbursement.

E. The National Meetings

Finally, TranS1 held a number of national meetings during the class period, which TranS1 senior management attended. At the 2009 national meeting, TranS1 allegedly promoted the use of the anterior (Category I) CPT code despite the fact that the AMA had already assigned the Category III code. A confidential witness attended the meeting and reported that the "official company line" was to encourage surgeons to avoid the Category III designation. According to the same confidential witness, this meeting was attended by Defendant Richard Randall, TranS1's CEO at the time.

Caplin alleges that each of these practices violated various federal healthcare fraud statutes, including the False Claims Act, 31 U.S.C. § 3729 *et seq.*, creating a substantial risk of regulatory investigation and civil and criminal penalties. Moreover, TranS1's investors allegedly

purchased TranS1 stock at an artificially-inflated price because TranS1 never disclosed that it was illicitly coaching surgeons to avoid the Category III designation.[4]

Instead of alerting investors to the risk of regulatory oversight and civil/criminal penalties, Caplin alleges that TranS1 submitted public statements regarding the Category III designation that were materially misleading and contained material omissions, all in violation of the federal securities laws. For example,[5] Caplin alleges that the following statement is materially misleading and contains material omissions because it fails to inform investors of TranS1's fraudulent scheme to advise surgeons to avoid the Category III designation:

> We will continue to work with our surgeon customers to generate published, peer reviewed clinical literature that demonstrates our procedure's clinical efficacy and safety. We will also work to leverage this data along with our AxiaLIF surgeon advocates, with payors to secure positive coverage decisions for the reimbursement of the AxiaLIF procedure.

Am. Compl. [DE-29] ¶ 89. Obviously, this statement does not contain any disclosures regarding TranS1's instructions to surgeons to bill the procedure as a Category I procedure or to bury the Category III code. TranS1 made multiple similar statements regarding reimbursement of the AxiaLIF procedure, none of which disclosed how TranS1 was allegedly coaching physicians to avoid the Category III designation. *See, e.g., id.* ¶¶ 59, 61, 64, 75, 78.

Caplin also alleges that all of TranS1's reported financial results during the class period contained material omissions because TranS1 failed to explain that the revenues were derived

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[4] Presumably, if the market had known about TranS1's fraudulent coaching of surgeons to use the Category I designation, the market would have known about the risk of regulatory oversight and the stock price would have been significantly less than what the class members paid.

[5] In light of the analysis below, the court does not find it necessary to recite all of the misleading statements/omissions contained in the amended complaint. Instead, the court provides a representative sample.

from the fraudulent reimbursement scheme. *Id.* ¶¶ 63, 67, 70, 71, 73, 77, 79, 81, 82, 84, 85, 87, 91, 92, 94. Caplin also cites to TranS1's statements that it was attempting to comply with various healthcare fraud statutes and regulations as materially misleading inasmuch as none of those statements disclosed the allegedly fraudulent reimbursement scheme. Caplin Resp. [DE-41] at 11; TranS1 Form 10K for period ending Dec. 31, 2010 [DE-33-19] at 15.

The risk associated with the purportedly fraudulent scheme "materialized" on October 18, 2011, when TranS1 disclosed that it had received a subpoena from the Department of Health and Human Services (DHHS). TranS1 filed an SEC form 8K, which disclosed the following:

> On or about October 6, 2011, TranS1 Inc. (the "Company") received a subpoena issued by the Department of Health and Human Services, Office of Inspector General, under the authority of the federal healthcare fraud and false claims statutes. The subpoena seeks documents for the period January 1, 2008 through October 6, 2011. The Company is cooperating with the government's request and is in the process of responding to the subpoena. The Company is unable to predict what action, if any, might be taken in the future by the Department of Health and Human Services, Office of Inspector General or other governmental authorities as a result of the matters related to this subpoena or what impact, if any, the outcome of these matters might have on its consolidated financial position, results of operations, or cash flows. No claims have been made against the Company at this time.

Am. Compl. [DE-29] ¶ 98. The Amended Complaint also cites an "analyst report to clients," which, on October 18, 2011, noted that:

> Management mentioned in our conversation that they have "let so many reps go in the last year and a half" (due to downsizing), which makes us think the subpoena could perhaps stem from allegations by a disgruntled former employee. Another speculation would be since about half of TranS1's revenues come from physicians still using the ALIF code (which provides reimbursement), rather than the designated T-code (which does not provide reimbursement), the issue could be due to reimbursement communications, although we think that the Company has been making strong efforts to educate physicians about correct coding. Note that ultimately the decision regarding which code to use lies in the hands of the physician.

Id. ¶ 99. When trading ended on October 18, TranS1's shares had fallen approximately 40%, closing at $1.85.

II. MOTION TO DISMISS

TranS1 now moves to dismiss the amended complaint, arguing, *inter alia*, that the complaint fails to adequately plead loss causation. In sum, the court agrees with TranS1 that the amended complaint fails to adequately plead loss causation.

A. Standard of Review

The purpose of a motion to dismiss under Rule 12(b)(6) is to test the legal sufficiency of the complaint, not to resolve conflicts of fact or to decide the merits of the action. *Edwards v. City of Goldsboro*, 178 F.3d 231, 243-44 (4th Cir. 1999). In considering a motion to dismiss, the court assumes the truth of all facts alleged in the complaint and the existence of any fact that can be proved, consistent with the complaint's allegations. *Erickson v. Pardus*, 551 U.S. 89, 94 (2007); *E. Shore Mkts., Inc. v. J.D. Assocs. Ltd. P'shp*, 213 F.3d 175, 180 (4th Cir. 2000). However, the "'[f]actual allegations must be enough to raise a right to relief above the speculative level' and the plaintiff must allege 'enough facts to state a claim to relief that is plausible on its face.'" *Wahi v. Charleston Area Med. Ctr., Inc.*, 562 F.3d 599, 615 n.26 (4th Cir. 2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). "[A] plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of a cause of action's elements will not do." *Twombly*, 550 U.S. at 555 (citations omitted); *see also Iqbal*, 556 U.S. at 678. Moreover, a court "need not accept the legal conclusions drawn from the facts" nor "accept as true unwarranted inferences, unreasonable conclusions, or arguments." *E. Shore Mkts.*, 213 F.3d at 180. The court may

consider "documents incorporated into the complaint by reference, and matters of which a court may take judicial notice" when deciding a Rule 12(b)(6) motion. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007).

Furthermore, private fraud claims (including securities fraud) are subject to heightened pleading standards. At least in the Fourth Circuit,[6] the loss causation element of a private securities fraud claim is governed by the heightened pleading requirements of Rule 9(b) of the Federal Rules of Civil Procedure and not the more liberal standard provided by Rule 8. *Katyle v. Penn Nat'l Gaming, Inc.*, 637 F.3d 462, 471 & n.5 (4th Cir. 2011). Rule 9(b) provides, "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b).

B. Discussion

The Securities and Exchange Act of 1934 proscribes (1) the "use or employ[ment] . . . of any . . . deceptive device," (2) "in connection with the purchase or sale of any security," and (3) "in contravention of" Securities and Exchange Commission "rules and regulations." 15 U.S.C. § 78j(b); *see also Dura Pharm. v. Broudo*, 544 U.S. 336, 341 (2005) (summarizing statute). The Securities and Exchange Commission (SEC), in turn, has adopted Rule 10(b)(5), which

[6] Caplin argues that loss causation is governed by the more liberal pleading standard associated with Rule 8 of the Federal Rules of Civil Procedure. That is not the law in the Fourth Circuit. *Katyle*, 637 F.3d at 471 & n.5 ("We review allegations of loss causation for 'sufficient specificity,' a standard largely consonant with Fed. R. Civ. P. 9(b)'s requirement that averments of fraud be pled with particularity."). And, at least in this case, this is not a purely academic distinction. This pleading standard has real consequences for Caplin's amended complaint, as discussed below. The court notes that loss causation is not subject to the pleading standards of the Private Securities Litigation Reform Act, 15 U.S.C. § 78u-4 *et seq*. The Private Securities Litigation Reform Act applies to the first two elements of a private securities fraud claim: materially false statement or omission and scienter. *Katyle*, 637 F.3d at 471 n.5.

proscribes "[the making] of any untrue statement of a material fact" or the omission of any material fact "necessary in order to make the statements made not . . . misleading." 17 C.F.R. § 240.10(b)-5; *see also Dura*, 544 U.S. at 341 (summarizing regulation). The courts have implied a private civil securities fraud action from the statute and regulation, which is similar to common law actions for fraud. *See Dura*, 544 U.S. at 341; *Blue Chip Stamps v. Manor Drug Stores*, 421 U.S. 723, 730, 744 (1975). The "basic elements" of a private securities fraud cause of action include:

> (1) *a material misrepresentation (or omission)*;
> (2) *scienter, i.e.*, a wrongful state of mind;
> (3) *a connection with the purchase or sale of a security*;
> (4) *reliance*, often referred to in cases involving public securities markets (fraud-on-the-market cases) as transaction causation;
> (5) *economic loss*; and
> (6) *loss causation, i.e.*, a causal connection between the material misrepresentation and the loss.

Dura, 544 U.S. at 341-42 (emphasis in original) (internal quotation marks and citations omitted). As noted, TranS1 argues that Caplin has failed to plead loss causation with sufficient particularity to survive a Rule 12(b)(6) motion to dismiss.

Loss causation refers to "the 'necessary causal link' between the defendant's alleged fraud and the plaintiff's economic harm." *Katyle*, 637 F.3d at 472 (quoting *Dura*, 544 U.S. at 346). The complaint must allege "facts to show . . . that the misrepresentation or omission was 'one substantial cause of the investment's decline in value.'" *Id.* (quoting *In re Mutual Funds Inv. Litig.*, 566 F.3d 111, 128 (4th Cir. 2009), *rev'd on other grounds*, *Janus Capital Grp., Inc. v. First Derivative Traders*, 131 S. Ct. 2296 (2011)). Stated in tort terms, "the defendant's misrepresentations (or other fraudulent conduct) [must] proximately cause[] the plaintiff's economic loss." *Dura*, 544 U.S. at 346. Loss causation must be alleged with "sufficient

specificity" to "'enable the court to evaluate whether the necessary causal link exists.'" *Katyle*, 637 F.3d at 471 (quoting *Teachers' Ret. Sys. of La. v. Hunter*, 477 F.3d 162, 186 (4th Cir. 2007)). "Because loss causation is fact-dependent, the specificity sufficient to plead loss causation will vary depending on the facts and circumstances of each case." *Id.* The plaintiff must at least "provide a defendant with some indication of the loss and the causal connection that the plaintiff has in mind." *Dura*, 544 U.S. at 347.

In *Dura*, the United States Supreme Court addressed the loss causation requirement in some detail. The Court concluded that a plaintiff cannot plead loss causation by alleging that he purchased a security at an inflated purchase price caused by the concealed fraud because "at the moment the transaction takes place, the plaintiff has suffered no loss." *Dura*, 544 U.S. at 342. The Court further explained that if the plaintiff sells "before the relevant truth begins to leak out, the misrepresentation will not have led to any loss. [But] [i]f the purchaser sells later after the truth makes its way into the marketplace, an initially inflated purchase price *might* mean a later loss." *Id.*

Thus, post-*Dura*, a plaintiff may not plead loss causation by simply alleging that he sold a security after its value dropped. Instead, the drop in purchase price must be tied to some disclosure of the fraud. *See id.*; *Teachers' Ret. Sys.*, 477 F.3d at 187. Post-*Dura*, the courts have struggled to give precise meaning to the phrase "after the truth makes its way into the marketplace." *Dura*, 544 U.S. at 342. As the Western District of Kentucky aptly noted, *Dura* leaves open questions regarding "what extent fraud must become known by the market before it can sufficiently be pled as causally related to economic loss . . . ." *In re Almost Family, Inc. Sec. Litig.*, 3:10-CV-00520-H, 2012 WL 443461, at *10 (W.D. Ky. Feb. 10, 2012). In an effort to

address this issue, federal courts have developed two somewhat distinct theories of loss causation: (1) corrective disclosure theory and (2) materialization of a concealed risk.

Under the corrective disclosure theory, "loss causation may be pleaded on the theory that the truth gradually emerged through a series of partial disclosures and that an entire series of partial disclosures caused the stock price deflation." *Lormand v. US Unwired Inc.*, 565 F.3d 228, 261 (5th Cir. 2009). In contrast, under the "materialization of a concealed risk" theory, a plaintiff must sufficiently allege "'negative investor inferences' drawn from the disclosures 'were a foreseeable materialization of the risk concealed . . . .'" *Katyle*, 637 F.3d at 477 & n.10 (quoting *In Re Omnicom Grp., Inc. Sec. Litig.*, 597 F.3d 501, 511 (2d Cir. 2010)). While the Fourth Circuit has not addressed the materialization of a concealed risk theory in detail, it has expressly acknowledged a plaintiff may successfully plead loss causation under it in two published opinions. *Katyle*, 637 F.3d at 477; *Teachers' Ret. Sys.*, 477 F.3d at 187 n.3.

In this case, although Caplin is proceeding under the materialization of a concealed risk theory, the court finds it prudent to analyze loss causation under both theories. As explained in detail below and as the parties point out in their briefing, some courts have allowed a plaintiff to plead loss causation on a corrective disclosure theory on facts similar to the facts alleged in Caplin's amended complaint.

Under either theory, analysis begins by identifying the particular disclosure or disclosures in which "the relevant truth began to leak out." *Dura*, 544 U.S. at 342. As noted above, the

disclosure in this case occurred when TranS1 notified the public that it had received a subpoena from the Department of Health and Human Services.[7] The disclosure reads,

> On or about October 6, 2011, TranS1 Inc. (the "Company") received a subpoena issued by the Department of Health and Human Services, Office of Inspector General, under the authority of the federal healthcare fraud and false claims statutes. The subpoena seeks documents for the period January 1, 2008 through October 6, 2011. The Company is cooperating with the government's request and is in the process of responding to the subpoena. The Company is unable to predict what action, if any, might be taken in the future by the Department of Health and Human Services, Office of Inspector General or other governmental authorities as a result of the matters related to this subpoena or what impact, if any, the outcome of these matters might have on its consolidated financial position, results of operations, or cash flows. No claims have been made against the Company at this time.

Am. Compl. [DE-29] ¶ 98.

1. Corrective Disclosure Theory

A number of courts have addressed the issue of whether the disclosure of a government investigation standing alone is a sufficient "revelation of the truth" to plead loss causation under the corrective disclosure theory. Unfortunately, the courts are fairly evenly split and the Fourth Circuit has not addressed the specific issue. Many courts outside this circuit have held that disclosure of a Government investigation standing alone is not sufficient to plead loss causation. *E.g.*, *Meyer v. Greene*, 710 F.3d 1189, 1201 (11th Cir. 2013) ("In our view, the commencement of an SEC investigation, without more, is insufficient to constitute a corrective disclosure . . . . To be sure, stock prices may fall upon the announcement of an SEC investigation, but that is

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[7] The amended complaint also references an "analyst's report to clients" in the "truth begins to emerge" section of the amended complaint. The analyst report discussed the TranS1 subpoena and suggested that the subpoena may relate to TranS1's "reimbursement communications with physicians." Am. Compl. ¶ 99. However, neither party mentions this disclosure in its briefing on the motion to dismiss and, thus, the court assumes it is not relevant for purposes of the loss causation analysis. Because the report was an "analyst report to clients," the court assumes that it was not publicly disclosed and thus not a sufficient revelation of the truth under *Dura*.

because the investigation can be seen to portend an added *risk* of future corrective action. That does not mean that the investigations, in and of themselves, reveal to the market that a company's previous statements were false or fraudulent."); *In re Maxim Integrated Prods., Inc. Sec. Litig.*, 639 F. Supp. 2d 1038, 1047 (N.D. Cal. 2009) ("[D]isclosures regarding compliance with an SEC investigation [and] subpoenas from the United States Attorney's office . . . do not reveal the alleged fraud. A reasonable investor may view these disclosures as indicators of risk because they reveal the potential existence of future corrective information. However, they do not themselves indicate anything more than a 'risk' or 'potential' that Defendants engaged in widespread fraudulent conduct. Thus, the Court finds that these statements are not corrective disclosures for which the Plaintiffs can plead loss causation."); *In re Take-Two Interactive Sec. Litig.*, 551 F. Supp. 2d 247, 284 (S.D.N.Y. 2008) (holding disclosure of grand jury subpoena from the Manhattan District Attorney's Office was not sufficient to satisfy *Dura* revelation of truth requirement because "there is a . . . distant relationship between the subject of the Manhattan District Attorney's announced investigation—Take-Two's general compensation practices—and the subject of the alleged fraud—Take-Two's options-granting practices").

Other courts have held that the disclosure of a Government subpoena is sufficient to plead loss causation, especially when accompanied by a stock price decline. *E.g.*, *In re Bradley Pharm., Inc. Sec. Litig.*, 421 F. Supp. 2d 822, 828 (D.N.J. 2006) (holding disclosure of SEC investigation into revenue recognition practices sufficient to satisfy *Dura* revelation of the truth requirement where immediate stock price decline followed disclosure); *In re Gentiva Sec. Litig.*, No. 10-CV-5064(ADS)(WDW), 2013 WL 1200334, at *32 (E.D.N.Y. Mar. 25, 2013) ("In the Court's view, until the Second Circuit or the Supreme Court dictate otherwise, an announcement

regarding a governmental investigation into the precise subject matter which forms the basis of the fraudulent practices at issue can qualify as a partial corrective disclosure for purposes of loss causation."); *In re Apollo Grp., Inc. Sec. Litig.*, No. CV-10-1735, 2011 WL 5101787, at *17 (D. Ariz. Oct. 27, 2011) ("[The announced SEC investigation into revenue recognition practices] could signal to a reasonable investor that there were improprieties in Apollo's revenue recognition practices, leading to a market reaction causing the stock price to drop 17.7%."). These courts have noted that *Dura* does not specify the precise amount of the fraud that must be revealed to the market to establish loss causation and that disclosure of the investigation signals to the market that the truth regarding the fraudulent scheme is beginning to "leak out." *In re Bradley Pharm.*, 421 F. Supp. 2d at 828-29; *In re Gentiva*, 2013 WL 1200334, at *31-32.

In re Bradley Pharmaceuticals, Inc. Securities Litigation, 421 F. Supp. 2d 822 (D.N.J. 2006) provides a useful example of this reasoning. Bradley Pharmaceuticals' press release disclosed that the SEC was conducting "an informal inquiry relating to the Company to determine whether there have been violations of the federal securities laws" and "in connection with the inquiry, the SEC staff has requested that the Company provide it with certain information and documents including with respect to revenue recognition and capitalization of certain payments." *Id.* at 824-25. Finding that the plaintiffs had adequately pled loss causation, the court reasoned, "[o]ur securities laws do not operate in a vacuum, Defendants' contention that the announcement of the SEC inquiry did not satisfy *Dura's* 'revelation of the truth' requirement fails to acknowledge the significance of the market reaction to the . . . disclosure [in which the stock price dropped approximately 26%]." *Id.* at 829.

At least two federal district courts have distinguished *In re Bradley Pharmaceuticals* on grounds that are particularly noteworthy in the context of the TranS1 disclosure. As the Northern District of Illinois explained:

> The press release [in *Bradley*] did, however, disclose an SEC inquiry relating to 'revenue recognition'—the precise subject matter of the alleged fraud. The causal link between the fraud and the share price decline after the announcement was thus sufficiently established: share price had been inflated by improper revenue recognition, and the disclosure of an SEC inquiry into improper revenue recognition dissipated that inflation, even if the particulars were as yet unrevealed. Here, in contrast, the [disclosure] attributed the earnings shortfall to factors wholly unrelated to the [allegedly fraudulent conduct].

In re Motorola Sec. Litig., 505 F. Supp. 2d 501, 548 (N.D. Ill. 2007), *overruled on other grounds by Merk & Co. v. Reynolds*, 559 U.S. 633 (2010), *as recognized in Antelis v. Freeman*, 799 F. Supp. 2d 854 (N.D. Ill. 2011). The Southern District of New York also distinguished *In re Bradley Pharmaceuticals* on similar grounds:

> The SEC's announced investigation in *In re Bradley Pharmaceuticals* dealt with the same subject matter—albeit, more generally—as did the alleged fraud, i.e., the defendant corporation's revenue recognition. Here, there is a more distant relationship between the subject of the Manhattan District Attorney's announced investigation—Take-Two's general compensation practices—and the subject of the alleged fraud—Take-Two's options-granting practices. Moreover, the SEC's announced investigation in *In re Bradley Pharmaceuticals* expressly involved violations of the federal securities laws, which obviously called into question the defendants' prior representations. The announced investigation in the instant case, however, made no mention of securities law violations, nor does an investigation by the Manhattan District Attorney's Office invariably involve prior public misrepresentations. Thus, the nexus between the disclosure and alleged fraud in this case is more tenuous than that in *In re Bradley Pharmaceuticals.*

In re Take-Two, 551 F. Supp. 2d at 284.

The court acknowledges this is a close case and that convincing arguments exist on both sides of the debate regarding pleading loss causation on the basis of a disclosure of a government investigation. However, under the particular facts and circumstances of this case, the court finds

that Caplin has not sufficiently pled loss causation under the corrective disclosure theory. *Katyle*, 637 F.3d at 471 (explaining "loss causation is a fact-dependent [inquiry]"). TranS1's disclosure can be distinguished from the *In re Bradley Pharmaceuticals* disclosure on precisely the same grounds the *In re Take-Two* and *In re Motorola* courts distinguished it. The TranS1 disclosure provides no information about the subject matter of the alleged scheme (advising surgeons to fraudulently code AxiaLIF procedures) and is thus too tenuously connected to the alleged misrepresentations/omissions to support loss causation under the corrective disclosure theory. *See In re Take-Two*, 551 F. Supp. 2d at 284 ("Here, there is a more distant relationship between the subject of the Manhattan District Attorney's announced investigation—Take-Two's general compensation practices—and the subject of the alleged fraud—Take-Two's options-granting practices."). It is true that the TranS1 disclosure indicates the subpoena was issued "under the authority of the federal healthcare fraud and false claims statutes," which suggests the subpoena is related to potential healthcare fraud or False Claims Act violations. However, similar to the Manhattan District Attorney's Office subpoena in *Take-Two*, this is far too general when compared to the actual subject of the alleged fraud to plead loss causation. Presumably, virtually any aspect of TranS1's business (a medical device sales company) is subject to a subpoena under the federal healthcare fraud statutes. The disclosure says nothing about AxiaLIF, insurance reimbursement practices, or what component of the company's business is under investigation.

Perhaps more importantly, the disclosure does not call into question any of TranS1's prior public statements. The fact that *In re Bradley Pharmaceuticals* received a subpoena from the SEC is significant because an SEC inquiry explicitly calls into question all of a company's prior public statements. *In re Take-Two*, 551 F. Supp. 2d at 284. Here, TranS1 received a subpoena

from the Department of Health and Human Services, a governmental agency that could be investigating virtually any aspect of TranS1's business, including practices that were never publicly disclosed. *See id.* at 285-86 ("[I]f a plaintiff relies upon a particular disclosure as the basis for his loss causation allegations, that disclosure must somehow reveal to the market some part of the truth regarding the alleged fraud."). In this regard, the court finds it noteworthy that the majority of the cases in which disclosure of a government investigation has been sufficient to plead loss causation involved disclosures of SEC investigations. *In re Bradley Pharm.*, 421 F. Supp. 2d at 824-25 (describing disclosure regarding SEC investigation); *In re Gentiva*, 2013 WL 1200334, at *29 (same); *In re Apollo Grp.*, 2011 WL 5101787, at *17 (same).

In addition to finding the corrective disclosure theory satisfied when a company announces a government investigation, courts have also expressed reluctance to dismiss securities fraud claims such as Caplin's based on public policy considerations. Assuming a securities fraud plaintiff may not establish loss causation based solely on an announced investigation, a savvy wrongdoer may avoid liability by simply announcing the existence of the investigation without in any way disclosing the subject matter of the investigation. *See In re Motorola*, 505 F. Supp. 2d at 544 ("Defendants' proposed rule would provide an expedient mechanism for wrongdoers to avoid securities fraud liability."). Investors with legitimate securities fraud claims would have to wait to sell a rapidly-declining security until after the fraudulent conduct was actually disclosed, which possibly may never occur. *See In re Gentiva*, 2013 WL 1200334, at *31-32 ("To embrace this notion [that disclosure of an investigation alone is not sufficient to plead loss causation] would be to preclude any type of action such as this, where there has been no conclusive finding of fraud by a government agency . . . .").

While the court acknowledges this is a persuasive argument, the court is persuaded that loss causation has not been adequately pled on the particular facts of this case. This case does not involve an SEC investigation, which calls into question all of a company's prior public statements. Public policy arguments that securities fraud defendants should not be allowed to structure disclosures in such a way as to avoid securities fraud liability are at their strongest when a company's prior public statements are already the subject of an investigation. As explained above, the DHHS investigation in this case may have had nothing to do with any of TranS1's prior public statements.

In addition, public companies already have significant incentives to disclose as little about a particular government investigation as possible. The more vague and equivocal the disclosure, presumably the less stock price decline may follow the announcement. While avoiding securities fraud liability may increase a particular company's incentive to submit vague disclosures, the court is convinced that it would do so only marginally.

Finally, allowing every securities fraud plaintiff to successfully plead loss causation based on the announcement of a government investigation raises countervailing public policy concerns. As the Supreme Court has explained, the securities laws were not intended to provide broad insurance against market risk. *Dura*, 544 U.S. at 347-48. The loss causation requirement is an important component of this principal because it guards "against [the] use [of private securities litigation] as an *in terrorem* device to force companies to settle claims simply to avoid the cost and burden of litigation." *Meyer*, 710 F.3d at 1196. In the court's estimation, allowing a plaintiff to plead loss causation solely on the basis of an announced investigation encourages the precise abusive litigation practices the securities laws are designed to protect against. Accepting

Caplin's theory of loss causation, a securities plaintiff can successfully plead loss causation every time a company receives a government subpoena and its share prices drop as a result. Under Caplin's proposed theory, the loss causation requirement becomes a pleading formality, which in turn encourages plaintiffs to file securities fraud cases for the sole reason of securing a settlement award.

2. Materialization of a Concealed Risk Theory

As noted, under the "materialization of a concealed risk" theory,[8] a plaintiff must sufficiently allege "'negative investor inferences' drawn from the disclosures 'were a foreseeable materialization of the risk concealed . . . .'" *Katyle*, 637 F.3d at 477 & n.10 (quoting *In Re Omnicom Grp.*, 597 F.3d at 511).[9] Caplin argues that TranS1's repeated failures to disclose its fraudulent reimbursement scheme, in which it "coached" surgeons to avoid the Category III designation, concealed a risk that the Department of Health and Human Services would initiate an investigation of the company. That risk materialized on October 18, 2011, when TranS1 disclosed that it had received a subpoena from DHHS, causing a significant decline in TranS1's share price.

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[8] The court notes that the materialization of a concealed risk theory has some critics. *Schleicher v. Wendt*, 618 F.3d 679, 683 (7th Cir. 2010) ("Although "materialization of risk" runs like a mantra through the parties' briefs, we do not think that it has any significance. The phrase appears in a few decisions to describe particular claims, but it is not a legal doctrine or anything special as a matter of fact." (citations omitted)).

[9] Curiously, Caplin's brief does not address the Fourth Circuit language regarding materialization of a concealed risk theory. Instead, Caplin cites to several Second Circuit opinions describing the theory. Some of these cases are addressed below. At any rate, the court does not find a significant difference between the Second Circuit and the Fourth Circuit with respect to the definition of materialization of a concealed risk. *See Katyle*, 637 F.3d at 477 (quoting Second Circuit opinion in *In re Omnicom Grp., Inc. Sec. Litig.*, 597 F.3d 501, 511 (2d Cir. 2010) for the definition of materialization of a concealed risk theory).

Based on a rote application of the Fourth Circuit language from *Katyle* regarding materialization of a concealed risk, Caplin's theory seems plausible. Caplin alleges that a foreseeable consequence of TranS1's material omissions regarding its efforts to coach surgeons to avoid the Category III designation was that the company would be subject to regulatory investigation and potential civil/criminal liability. When TranS1 disclosed the investigation, investors allegedly drew "negative inferences" about the company, causing a decline in stock value. *Katyle*, 637 F.3d at 477 & n.10.

Caplin argues that the court should stop here and find that he has adequately pled loss causation pursuant to the materialization of a concealed risk theory. The court is not persuaded. In the Fourth Circuit, loss causation must be pleaded with particularity under Rule 9(b) of the Federal Rules of Civil Procedure. *Katyle*, 637 F.3d at 471. The inquiry "is fact-dependent [and] the specificity sufficient to plead loss causation will vary depending on the facts and circumstances of each case." *Id.* Caplin's amended complaint must allege, with particularity, how disclosure of the subpoena proximately caused the class members' losses. Given the facts of this particular case, the court is convinced that Caplin cannot do so.

Caplin's materialization of a concealed risk theory fails for at least three reasons. First, Caplin's theory would essentially write the *Dura* revelation of the truth requirement out of the loss causation analysis. Second, in cases where the theory has been adequately pled, the causal connections between the events constituting materialization of the risk and the alleged misrepresentations were much stronger than what is alleged in this case. Third, allowing Caplin to plead loss causation under materialization of a concealed risk theory in this case, where the disclosure did not reveal the subject of the purported fraud, would mean that every time a

company receives a subpoena from a government agency, a securities fraud plaintiff could successfully allege loss causation. That is simply inconsistent with the purpose of private securities fraud claims.

As explained above, *Dura* imposes an overarching requirement on every securities fraud plaintiff: to successfully plead loss causation, a plaintiff must demonstrate how the "relevant truth beg[an] to leak out." *Dura*, 544 U.S. at 342. A plaintiff may not avoid this requirement by simply labeling his theory of the case "materialization of a concealed risk." *See Teachers' Retirement*, 477 F.3d at 187 n.3 ("In [a case proceeding under a materialization of a concealed risk theory], the plaintiffs would not need to identify a public disclosure that corrected the previous, misleading disclosure because *the news of the materialized risk would itself be the revelation of the fraud* that caused the plaintiff's loss." (emphasis added)); *In re Vivendi Universal, S.A. Sec. Litig.*, 634 F. Supp. 2d 352, 365 (S.D.N.Y. 2009) ("To demonstrate the connection between the statements and the events—termed 'materializations of the concealed risk'—plaintiffs must show (1) that these events were foreseeable consequences of the alleged fraud; and (2) *that these events revealed new information previously concealed by defendants' alleged fraud*." (emphasis added) (citations omitted)).

Caplin's own definition of the materialization of a concealed risk theory demonstrates how creative plaintiffs can use the theory to avoid the *Dura* revelation of the truth requirement. Caplin defines the theory as follows: "[u]nder the 'materialization of the risk' approach to loss causation recognized in *Lentell*, a plaintiff may establish loss causation by showing that the defendant's conduct concealed or caused the plaintiff to misapprehend a foreseeable risk that later materialized, causing a decline in the value of the subject security." Caplin Resp. [DE-41]

at 27. The definition, conveniently for the plaintiffs, entirely fails to address the revelation of the truth requirement. The court agrees that pleading loss causation does not require a plaintiff to specifically point to a prior alleged misrepresentation and show how that misrepresentation was later corrected by the defendant. *In re Motorola*, 505 F. Supp. 2d at 542. However, *Dura* requires more than what has been alleged in this case. The subpoena in this particular case does not reveal to the investing public, in any meaningful way, the alleged fraud. The DHHS subpoena could have related to an entirely separate (and nonpublic) aspect of TranS1's business.

The court is also persuaded that cases in which the theory has been found viable are sufficiently distinguishable from facts of this case. In *In re Massey Energy Co. Sec. Litig.*, 883 F. Supp. 2d 597 (S.D. W.Va. 2012), the district court considered whether an explosion at a coal mining plant constituted materialization of a concealed risk and was a sufficient revelation of the truth to plead loss causation. *Id.* at 624-26. Despite repeated safety violations, the *Massey* defendants continued to assure the public that its priority was the safety of its workers and that it had an impeccable safety record. *Id.* at 604-05. However, the fraudulent nature of these statements was revealed when an explosion killing twenty-nine coal miners occurred at one of Massey's mines. *Id.* Importantly, on-site investigations of the explosion revealed to the public that the explosion was caused by basic mine safety violations. *Id.* at 626. The *Massey* court held that the plaintiffs had successfully pled loss causation, explaining "the explosion and the cause of the explosion revealed to the market the fraudulent nature of which Plaintiffs complain, specifically, that Defendants misled the market about the safety at its mines and its commitment to put [safety over production]." *Id.*

In *In re Vivendi Universal, S.A. Securities Litigation*, 634 F. Supp. 2d 352 (S.D.N.Y. 2009), the district court denied Vivendi's motion for summary judgment on loss causation grounds, finding that the plaintiffs' materialization of a concealed risk theory was viable and that genuine issues of material fact precluded summary judgment. *Id.* at 365-69. In *Vivendi*, the defendants made a number of public disclosures allegedly inflating its reported cash flow levels and minimizing its reported debt obligations. *Id.* at 366-67. The plaintiffs argued that each of these allegedly fraudulent statements concealed a substantial liquidity risk, and identified at least eleven disclosures that constituted materialization of that risk. *Id.* Most of the disclosures involved "quick unexpected asset sales or credit rating downgrades." *Id.* at 367.

As explained above, the *In re Vivendi* court defined materialization of a concealed risk theory as follows: "[t]o demonstrate the connection between the statements and the events—termed 'materializations of the concealed risk'—plaintiffs must show (1) that these events were foreseeable consequences of the alleged fraud; and (2) that these events revealed new information previously concealed by defendants' alleged fraud." *Id.* at 365. Finding that the credit ratings downgrades and the swift asset sales revealed new information about the allegedly fraudulently-concealed liquidity risk, the court found plaintiff's materialization of a concealed risk theory viable. *Id.* at 367-69. The court explained that genuine issues of material fact precluded summary judgment because the ratings downgrades and asset sales potentially revealed to the market previously concealed information regarding Vivendi's liquidity problems. *Id.*

The court acknowledges that these cases lend some support to Caplin's materialization of a concealed risk theory. In both cases, the events constituting materialization of the risk—the explosion in *Massey* and the ratings downgrades/asset sales in *Vivendi*—revealed new

information about the risks concealed by the fraud, but neither event specifically corrected a prior misrepresentation or omission. The disclosure of the subpoena in this case, as explained above, reveals nothing about the particular fraudulent scheme. However, at least arguably, it reveals new information about the risk concealed by TranS1's allegedly fraudulent statements: that TranS1 was placing itself at significant risk of government investigation and civil liability if it continued to "coach" surgeons to avoid the Category III designation.

Nevertheless, the court finds that *Vivendi* and *Massey* are sufficiently distinguishable. In both *Vivendi* and *Massey*, the causal connections between the events constituting materialization of the risk and the allegedly fraudulent statements were particularly strong. In *Massey*, the company had a history of mining accidents and safety violations when it embarked on a corporate image campaign assuring the public that it had become one of the safest coal mining operations in the country. *In re Massey Energy*, 883 F. Supp. 2d at 602-05. The explosion in that case immediately called into question any prior public representations regarding mine safety. Similarly, the ratings downgrades/asset sales in Vivendi immediately called into question the company's prior statements indicating that it had adequate cash flow and minimal debt obligations. *In re Vivendi*, 634 F. Supp. 2d at 366-67.

Conversely, the disclosure that TranS1 received a subpoena from DHHS does not sufficiently relate to the prior public statements regarding AxiaLIF to establish loss causation under these particular facts. The disclosure that TranS1 received a subpoena from DHHS does not immediately call into question TranS1's prior public statements regarding AxiaLIF and the Category III designation in the way the disclosures in *Vivendi* and *Massey* called into question the prior public statements of those companies. Had the disclosure indicated the investigation was

related to AxiaLIF or insurance reimbursement, *Vivendi* and *Massey* would provide better support for Caplin's argument. Under the particular facts of this case, however, the connection between the disclosure of the subpoena and the prior alleged misstatements is too attenuated to successfully plead loss causation. *See Katyle*, 637 F.3d at 472 ("[T]he complaint must allege a sufficiently direct relationship between the plaintiff's economic loss and the defendant's fraudulent conduct. '[I]f the connection is attenuated . . . a fraud claim will not lie. That is because the loss causation requirement—as with the foreseeability limitation in tort—is intended to fix a legal limit on a person's responsibility, even for wrongful acts.'" (quoting *Lentell v. Merrill Lynch & Co., Inc.*, 396 F.3d 161, 174 (2d cir. 2005))).

Finally, allowing this particular claim to proceed under the *Vivendi* approach to loss causation exposes essentially every company that receives a government subpoena to a securities fraud claim. As noted, the loss causation requirement is designed to limit, not extend, a particular company's exposure to private securities fraud claims. Assume a company receives a subpoena from a government agency and a securities fraud plaintiff pleads loss causation under the *Vivendi* approach to materialization of a concealed risk. The *Vivendi* court defined materialization of a concealed risk as "(1) . . . the[] events [constituting materialization of the concealed risk] were foreseeable consequences of the alleged fraud; and (2) . . . the[] events revealed new information previously concealed by defendants' alleged fraud." *In re Vivendi*, 634 F. Supp. 2d at 365. By defining the "event constituting materialization of a concealed risk" as the receipt of a government subpoena, a creative plaintiff successfully pleads loss causation in nearly every case in which a company receives a subpoena from a government agency. A plaintiff would simply need to allege, as Caplin does here, that the company's prior public

statements failed to disclose some wrongful conduct relating to the general subject matter of the subpoena. At the motion to dismiss stage, the plaintiff would argue that the risk of government investigation was a foreseeable consequence of the wrongful conduct (as it always is), and that risk materialized when the company received the subpoena. Under this approach, loss causation is satisfied every time a company discloses that it received a government subpoena. By defining the "event constituting materialization of a concealed risk" as the receipt of a government subpoena, the loss causation requirement becomes a pleading formality. This is inconsistent with the Fourth Circuit's heightened pleading requirements for loss causation and with the policy goals of the securities laws.

3. Amending the Complaint

For the foregoing reasons, the court finds that Caplin has not sufficiently alleged loss causation in the amended complaint. The court also finds that allowing further amendment would be futile. *See In re PEC Solutions, Inc. Sec. Litig.*, 418 F.3d 379, 391 (4th Cir. 2005) ("Leave to amend need not be given when amendment would be futile."). The class in this case consists of "all persons other than defendants who purchased TranS1 securities between February 23, 2009 and October 17, 2011." Am. Compl. [DE-29] ¶ 1. The materialization of the concealed risk/corrective disclosure occurred, if at all, on October 18, 2011 when the share price fell approximately 40% after disclosure of the subpoena. Caplin has submitted a number of "requests for judicial notice" in which further information about the allegedly fraudulent conduct has potentially become public after the October 18, 2011 disclosure. Requests for Judicial Notice [DE-43, -46]. However, none of these events would be sufficient for purposes of alleging loss causation because the stock price did not drop after any of these purported disclosures. *See*

Baxano Surgical, Inc. Historical Stock Prices, NASDAQ, http://www.nasdaq.com/symbol/baxs/historical (providing historical stock prices for TranS1 and showing no appreciable stock declines on any of the disclosure dates provided in Caplin's requests for judicial notice); Consent Motion to Modify Case Caption [DE-45] (explaining Tran1 changed its corporate name after it purchased Baxano). To allege causation—proximate or actual—the disclosure must have caused a decline in the security's value. *See Dura*, 544 U.S. at 346 ("[The securities laws require] that a plaintiff prove that the defendant's misrepresentation (or other fraudulent conduct) proximately caused the plaintiff's economic loss."); *Lentell*, 396 F.3d at 176 ("[P]laintiffs allege no loss resulting from the market's realization that the opinions were false, or that [the defendant] concealed any risk that could plausibly (let alone foreseeably) have caused the plaintiffs' loss."). Thus, because the only significant stock decline in this case occurred after the October 18, 2011 disclosure, and that disclosure is insufficient to plead loss causation, the court finds that amendment would be futile.

4. Section 20(a) Claim

Caplin also asserts a claim for control person liability under § 20(a) of the Securities and Exchange Act of 1934. However, a claim for control person liability requires "a predicate violation § 10(b)." *In re Mutual Funds Inv. Litig.*, 566 F.3d at 129. Because Caplin's § 10(b) claim is dismissed, his § 20(a) claim must also be dismissed.

CONCLUSION

TranS1's motion to dismiss [DE-34] is ALLOWED and the amended complaint is DISMISSED WITH PREJUDICE. TranS1's motion to modify case caption [DE-45] is DENIED AS MOOT. The parties various requests for judicial notice [DE-30, -43, -46] are ALLOWED. The Clerk of Court is DIRECTED to close this case.

SO ORDERED.

This the 19th day of September, 2013.

James C. Fox
JAMES C. FOX
Senior United States District Judge